IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Michael Kelley, *et al.*,

Plaintiff

v.

Insys Therapeutics, Inc., *et al.*,

Defendant

Case No. 3:18CV1774

ORDER

This is a products liability case.

Plaintiff Michael Kelley (Michael) sustained serious injuries when he overdosed on a prescription opioid, Subsys, which he used to treat lower back pain, knee pain, and carpal tunnel syndrome. He and his wife, plaintiff Julie Kelley (Julie) sue defendants Insys Therapeutics, Inc., Insys Pharma, Inc., and Insys Manufacturing, LLC, which manufactured Subsys.

Subsys is primarily prescribed to treat cancer pain, but plaintiffs allege that defendants encouraged using Subsys for the "off-label" purpose of treating general pain. This is so, plaintiffs claim, even though defendants knew Subsys could cause dangerous side effects and was highly addictive.

Plaintiffs raise thirteen claims against defendants. Their claims include statutory and common-law strict liability claims and common-law claims for negligence, negligent misrepresentation, fraud, false advertising, and unjust enrichment. Plaintiffs also allege that

defendants violated the Ohio Consumer Sales Practices Act.[1] Finally, Julie asserts claims for loss of consortium and negligent infliction of emotional distress.[2]

Jurisdiction is proper under 26 U.S.C. § 1332.

Now pending is defendants' motion to dismiss (Doc. 6). For the reasons that follow, I grant the motion in part and deny it in part.

Background

Michael began taking Subsys in September, 2013, when his pain management doctor recommended the drug to treat the pain in his lower back and knee and his carpal tunnel pain. (Doc. 1-2 at 3, ¶ 9). The doctor, whom Michael began seeing in 2008, prescribed Subsys to supplement his then-current treatment. That treatment included other opioids and injection therapy. (Doc. 1-2 at 3, ¶ 7-8).

Subsys is a potent painkiller. It is a fentanyl spray that, plaintiffs allege, is stronger than morphine and heroin. (*Id.* at 3, ¶ 10). In January, 2012, the FDA approved Subsys "for the management of breakthrough cancer pain in patients 18 years of age or older who are already receiving and tolerant to opioid therapy for their underlying cancer pain." (*Id.* at 4, ¶ 11). Michael's prescription, then, was for an "off-label" (*i.e.*, not FDA approved) use.

Plaintiffs allege that defendants knew that non-cancer patients could suffer serious side effects from Subsys and become addicted to it. (Doc. 1-2 at 4, ¶ 12). They further allege that, despite this knowledge, defendants "push[ed]" the drug on non-cancer patients and "paid

[1] For brevity, I refer to this claim as the "consumer protection claim" or the "OCSPA claim."

[2] Plaintiffs also assert a punitive damages claim in their complaint but acknowledge in their opposition brief that "a cause of action for 'Punitive Damages' is generally not considered a stand alone claim under Ohio law." (Doc. 12 at 18). I therefore dismiss that claim without prejudice to plaintiffs' right to seek to recover such damages in further proceedings.

Doctors . . . thousands of dollars to promote Subsys® at speaking engagements that were a 'sham.'" (*Id.* at 6, ¶¶ 26, 28).

Michael was "highly dependent" on Subsys. (*Id.* at 4-5, ¶ 19). On or about July 21, 2016, Julie found him "unresponsive with respiratory failure in their home" from an accidental Subsys overdose. (*Id.* at 5, ¶ 20). Emergency response personnel gave Michael two doses of Narcan and intubated him. (*Id.*).

Michael was hospitalized in intensive care after the overdose until August, 2016. (*Id.* at 5, ¶ 22). The overdose caused him "acute respiratory failure," requiring ventilator treatment. (*Id.* at 5, ¶ 21). He also suffered "hypoxia, aspiration pneumonia, renal failure, multiorgan system failure, liver failure, altered mental status, and stroke." (*Id.*). Hospital personnel took Michael off Subsys, causing him "painful withdrawal symptoms." (*Id.*).

Standard of Review

To survive a motion to dismiss, a complaint "must contain sufficient factual matter, accepted as true, to state a claim that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* At this stage, I must "draw all reasonable inferences in favor of [plaintiffs]." *Courtright v. City of Battle Creek*, 839 F.3d 513, 520 (6th Cir. 2016).

Analysis

I. FDCA Preemption

Defendants argue that the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301, *et seq.*, impliedly preempts plaintiffs' claims. (Doc. 6-1 at 5-12).

The FDCA regulates, among other things, prescription drugs. The statute provides that "all . . . proceedings for the enforcement, or to restrain violations of" the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Accordingly, "[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who is authorized to file suit for noncompliance with its substantive provisions." *Loreto v. Procter & Gamble Co.*, 515 Fed. App'x 576, 579 (6th Cir. 2013) (quoting *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001) (internal quotations omitted)); *see also Warstler v. Medtronic, Inc.*, 238 F. Supp. 3d 978, 991 (N.D. Ohio 2017) (Carr, J.).

The FDCA, then, impliedly preempts "state-law claim[s that are] in substance (even if not in form) a claim for violating the FDCA." *Loreto*, *supra*, 515 Fed. App'x at 579 (internal quotations and citation omitted). "If [a] claim would not exist in the absence of the FDCA, it is impliedly preempted." *Id.* (citing *Buckman*, *supra*, 531 U.S. at 353). "[S]avvy plaintiffs" cannot usurp the FDA's exclusive enforcement authority by "label[ing] as arising under a state law for which there exists a private enforcement mechanism a claim that in substance seeks to enforce the FDCA." *Id.*

Defendants assert that plaintiffs' claims, in substance, seek redress for FDCA violations. (*See* Doc. 6-1 at 7). Plaintiffs respond that their claims arise under state law and, therefore, are not preempted. (Doc. 12 at 4-8).

A. The FDCA Impliedly Preempts Claims Based Solely on Off-Label Use and Promotion

Defendants argue that plaintiffs' claims are preempted because they arise out of Michael's "off-label" use of Subsys to treat non-cancer pain. (Doc. 6-1 at 7-12).

"The concept of 'off-label use and promotion' is derived from and defined by the FDCA regulatory system and has no state-law equivalent." *McDaniel v. Upsher-Smith Pharms., Inc.*,

229 F. Supp. 3d 707, 711 (W.D. Tenn. 2017) (quoting *Hafer v. Medtronic, Inc.*, 99 F. Supp. 3d 844, 857 (W.D. Tenn. 2015)); *accord Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 628 (W.D. Mich. 2015).[3] Accordingly, "any claim based *solely* on off-label promotion is impliedly preempted." *McDaniel*, *supra*, 229 F. Supp. 3d at 711 (emphasis added).

This is not to say, however, that *all* claims involving allegations of off-label promotion are preempted. If independent state law grounds support such claims, the FDCA does not preempt them. *See, e.g.*, *Arters v. Sandoz, Inc.*, 921 F. Supp. 2d 813, 819-20 (S.D. Ohio 2013); *In re Nat'l Prescription Opiate Litig.*, 2018 WL 4895856, *23-24 (N.D. Ohio) (Ruiz, M.J.); *report and recommendation adopted as to preemption analysis*, 2018 WL 6628898 (N.D. Ohio) (Polster, J.).

Defendants assert that plaintiffs seek to hold defendants liable for promoting Subsys for off-label use. (Doc. 6-1 at 7-12). Plaintiffs respond that their claims are not "for off-label marketing" but "allege [that] Defendants engaged in off-label marketing within the context of garden variety state law claims." (Doc. 12 at 9).

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[3] Plaintiffs argue that cases involving medical devices and generic drugs do not apply where, as here, the subject product is a brand-name drug. I disagree. Notably, in *Loreto, supra* (which plaintiffs cite), a name-brand drug case, the Sixth Circuit relied on a medical device case, *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009), interpreting the Supreme Court's decision in *Buckman*, 531 U.S. 341. (*See* Doc. 12 at 10 (citing 515 Fed. App'x 576)). Moreover, plaintiffs argue that "this case is like *Arters v. Sandoz Inc.*, 921 F. Supp. 2d 813 (S.D. Ohio 2013)," a generic drug case. (Doc. 12 at 11 (citing *id.*)). Plaintiffs cannot at the same time argue that generic drug and medical device cases do not apply and cite such cases in support of their opposition.

Plaintiffs also argue that the Supreme Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009) applies in this case. I disagree. In *Wyeth*, the Court held that the FDCA does not preempt products liability claims based on inadequate warnings on brand name drugs' labels. But that case did not take up the narrower issue of whether such claims are preempted when they allege that a manufacturer failed to warn of the dangers of a drug's off-label use.

As discussed *infra*, both parties paint with too broad a brush. Although some of plaintiffs' claims are solely for off-label promotion and are preempted, independent state-law grounds support others, which survive plaintiffs' motion to dismiss.

B. The FDCA Preempts Plaintiffs' Negligence Claim

The FDCA preempts plaintiffs' negligence claim (Count one) because it alleges that defendants breached a duty by selling Subsys "in an 'off-label' manner . . . rather than for uses approved by the FDA." *See McDaniel*, *supra*, 229 F. Supp. 3d at 712-13 (dismissing negligence and negligence *per se* claims).

The court in *McDaniel* dismissed plaintiffs' negligence and negligence *per se* claims as relying solely on off-label promotion. *Id.* Similarly, the court in *Thorn*, *supra*, dismissed negligence and gross negligence claims based on the defendant's "fail[ure] to refrain from promoting off-label use of" its device. 81 F. Supp. 3d at 629-30.

Here, plaintiffs allege that defendants breached a duty by "promot[ing] . . . Subsys®" for purposes other than "management of breakthrough cancer pain." (Doc. 1-2 at 7, ¶¶ 34-35). The FDCA preempts this claim because, in substance, it seeks recovery for off-label promotion. *See McDaniel*, *supra*, 229 F. Supp. 3d at 712-13; *Thorn*, *supra*, 81 F. Supp. 3d at 629-30.

C. The FDCA Preempts Plaintiffs' Inadequate Warning Claims

The FDCA likewise preempts plaintiffs' claims for strict liability due to inadequate warning (Counts three and four).

First, Count three, in part, relies on an allegation that "Defendants failed to provide proper and full information as to the safety of Subsys® to the U.S. Food and Drug Administration." (Doc. 1-2 at 11, ¶ 59). The FDCA clearly preempts such "fraud-on-the-FDA claims under state tort law." *Buckman*, *supra*, 531 U.S. at 348.

Further, plaintiffs' claims rely on alleged "representations and omissions during off-label promotion." *See Thorn, supra,* 81 F. Supp. 3d at 625-28. In *Thorn,* the court held that the FDCA preempted plaintiffs' claim that defendants "'fail[ed] to warn physicians and the public in general of the dangers of off-label use.'" 81 F. Supp. 3d at 625-28 (quoting complaint); *see also Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1011 (S.D. Ohio 2016) (dismissing similar failure-to-warn claims).

Here, too, plaintiffs allege that defendants "fail[ed] to warn of the increased risks and danger of harm inherent in Subsys for individuals without cancer," that is, those using Subsys for an off-label purpose. (Doc. 1-2 at 11, ¶ 61; *see also id.* at 12, ¶¶ 67-68). The FDCA, therefore, preempts the inadequate warning claims. *See Thorn, supra,* 81 F. Supp. 3d at 625-28; *see also Aaron, supra,* 209 F. Supp. 3d at 1011 (dismissing similar failure-to-warn claim).[4]

D. The FDCA Does Not Preempt Plaintiffs' Negligent Misrepresentation, Fraud, Consumer Protection, False Advertising, and Design Defect Claims

The FDCA does not, however, preempt plaintiffs' negligent misrepresentation, fraud, consumer protection, and false advertising claims. Those claims rely on the independent ground that defendants "promoted [Subsys] in a fraudulent . . . way." *See Arters, supra,* 921 F. Supp. 2d at 819-20.

The court in *Arters* held that the FDCA did not preempt plaintiffs' fraud and other claims because those claims alleged more than off-label promotion. *Id.* Likewise, the court in *In re National Prescription Opiate Litigation, supra,* held that the FDCA did not preempt claims

[4] Plaintiffs' third cause of action begins by alleging that Subsys, irrespective of how it is used, posed a risk of serious harm and that defendants failed to warn consumers of such harm. (*See* Doc. 1-2 at 10, ¶¶ 54-58). The remainder of that claim, however, makes clear that it is about off-label use only: "Defendants' failure to warn of the increased risks and danger of harm inherent in Subsys® *for individuals without cancer,* as described above, created an unreasonable danger to users of this product." (*Id.* at 11, ¶ 61 (emphasis added)).

alleging "that Defendants misrepresented the risks associated with off-label opioid use." 2018 WL 4895856 at *23.

Plaintiffs similarly allege more than off-label promotion. Indeed, they claim that defendants: "willfully deceived" plaintiffs and others "as to the health risks and consequences of the use of Subsys®," "failed to disclose material facts regarding the safety of Subsys®," and misrepresented its appropriate use. (Doc. 1-2 at 8, ¶ 42; *see also id.* at 17, 19-20, ¶¶ 91, 105, 110). Accordingly, the FDCA does not preempt the negligent misrepresentation, fraud, consumer protection, and false advertising claims.

The FDCA also does not preempt plaintiffs' design defect claims because they allege more than off-label promotion.

In *Arters*, *supra*, the court held the FDCA did not preempt plaintiffs' design defect claims that alleged a breach of duty "to refrain from a selling a product that is . . . unreasonably dangerous." *Compare* 921 F. Supp. 2d at 818 *with Aaron*, *supra*, 209 F. Supp. 3d at 1011 (dismissing design defect claim that "rel[ied] on Defendants' off-label promotion" only). Likewise, here, plaintiffs claim that Subsys was defective because it was "unsafe in that [it] caused serious injuries and death as a result of addiction and overdose," whether used for on- or off-label purposes. (Doc. 1-2 at 14, ¶ 76; *see also id.* at 15, ¶ 84). Accordingly, the FDCA does not preempt plaintiffs' design defect claims.

II. The Ohio Products Liability Act

Defendants alternatively argue that the Ohio Products Liability Act (OPLA), Ohio Rev. Code §§ 2307.71, *et seq.* abrogates plaintiffs' common-law claims and their consumer protection claim.

"Sections 230707.71 to 2307.80 of the [Ohio] Revised Code are intended to abrogate all common law product liability claims or causes of action." Ohio Rev. Code. § 2307.71(B). Products liability claims

> seek[] to recover compensatory damages from a manufacturer or supplier for death, physical injury to person, emotional distress, or physical damage to property other than the product in question, that allegedly arose from any of the following:
> (a) The design, formulation, production, construction, creation, assembly, rebuilding, testing, or marketing of that product;
> (b) Any warning or instruction, or lack of warning or instruction, associated with that product;
> (c) Any failure of that product to conform to any relevant representation or warranty.

Id. at 2307.71(A)(13)(a)-(c).

A. Plaintiffs' Third and Fifth Causes of Action Do Not Sufficiently Allege OPLA Violations

First, plaintiffs admit that the OPLA abrogates their third and fifth causes of action for strict products liability "to the extent not brought under the OPLA." (Doc. 12 at 17). They do not, however, respond to defendants' argument that the "passing citation to the entire OPLA" at the end of each of those counts is "fatal to those claims." (Doc. 6-1 at 13-14).

I agree with defendants that these two claims do not sufficiently allege OPLA violations.

"Claims that are authorized by the OPLA should be pled with reference to the applicable provision of the OPLA." *Kodger v. Zimmer Biomet Holdings, Inc.*, 2017 WL 4348997, *5 (N.D. Ohio) (Gwin, J.) (internal quotations and citations omitted) (dismissing OPLA manufacturing defect claim that cited design defect statute). I therefore dismiss plaintiffs' third and fifth causes

of action because plaintiffs do not identify the applicable OPLA provisions but generally seek relief "pursuant to . . . applicable state statutes." (*See* Doc.1-2 at12 ¶ 65; *id.* at 14, ¶ 81).[5]

B. The OPLA Does Not Abrogate Plaintiffs' Misrepresentation Claims to the Extent They Allege Active Misrepresentation

Next, defendants argue that "[t]he OPLA abrogates Plaintiffs' fraud- and misrepresentation-based claims."[6] (Doc. 6-1 at 15 (internal citation omitted)).

The OPLA "broadly defines product liability claims as including those where the alleged injuries arise from the 'formulation' of the product or '*any* warning or instruction, or lack of warning or instruction, associated with that product.'" *Hogue v. Pfizer, Inc.*, 893 F. Supp. 2d 914, 917 (S.D. Ohio 2012) (quoting Ohio Rev. code. § 2307.71(A)(13)(b)). Accordingly, courts have held that the OPLA abrogates failure to warn claims artfully pled as fraud or misrepresentation claims. *See, e.g., id.*

Plaintiffs' misrepresentation claims allege that defendants "engaged in fraud by both failing to disclose material facts and by actively misrepresenting information about [Subsys's] safety." *Stratford v. SmithKline Beecham Corp.*, 2008 WL 2491965, *8 (S.D. Ohio). I must

[5] Unlike the court in *Kodger*, *supra*, I do not grant plaintiffs leave to amend their complaint to identify the applicable OPLA provisions. *See* 2017 WL 4348997 at *5. Plaintiffs' fourth and sixth causes of action raise parallel products liability claims under the respective OPLA provisions. (*See* Doc. 1-2 at 12-13, ¶¶ 66-72; *id.* at 14-16, ¶¶ 82-88). Plaintiffs therefore suffer no prejudice from my decision to dismiss the third and fifth causes of action. I note, however, that I have dismissed plaintiffs' third and fourth causes of action for strict liability due to inadequate warning on FDCA-preemption grounds.

Further, in light of my findings herein, I decline to determine whether the learned intermediary doctrine defeats plaintiffs' claims that arise from a failure to warn. (*See* Doc. 6-1 at 16-17).

[6] These claims include counts two, seven, and nine for negligent misrepresentation, fraud, and false advertising, respectively. I collectively refer to these claims as the "misrepresentation claims."

dismiss plaintiffs' misrepresentation claims to the extent they rely on allegations that defendants "failed to disclose" "the truth about Subsys®." (*See* Doc. 1-2 at 17, ¶ 93; *see also id.* at 9, 20 ¶¶ 45, 112). *Stratford, supra*, 2008 WL 2491965 at *8 (holding OPLA abrogated claims based on "fraudulent omission").

But "the OPLA does not necessarily preclude *all* claims of fraud and misrepresentation." *Id.* at 918 (citing *Stratford, supra*, 2008 WL 2491965 at *8). Courts in this circuit have held that such claims are viable where they are "based on a general duty not to actively deceive." *Id.* (citing *Stratford, supra*, 2008 WL 2491965 at *8; *Glassner v. R.J. Reynolds Tobacco Co.*, 223 F.3d 343, 348-49 (6th Cir. 2000)).

For example, in *Hutchens v. Abbot Laboratories, Inc.*, 2016 WL 5661582, *12 (N.D. Ohio) (Gwin, J.), the court held that the OPLA did not abrogate plaintiffs' fraud claim "because it allege[d] violation[s] of Defendants' general duty not to deceive consumers and physicians." Specifically, plaintiffs claimed that defendants represented that their drug "was as safe or safer than" other drugs in the same category and that it did not cause birth defects. *Id.* at *12.

Similarly, an Illinois court applying Ohio law held that the OPLA did not abrogate a fraudulent concealment claim where a dishwasher manufacturer "represent[ed] that the dishwashers were safe for use." *Elward v. Electrolux Home Prods., Inc.*, 264 F. Supp. 3d 877, 896 (N.D. Ill. 2017).

Finally, the court in *Stratford, supra*, explained that plaintiff's fraud claim alleging that a drug manufacturer "misrepresented the truth about [the drug's] safety . . . [was] not necessarily abrogated by the OPLA because [it] may implicate the more general duty not to deceive." 2008 WL 2491965 at *8-9 (dismissing fraud claim for failure to plead with particularity).

But there is some conflict on this issue. At least two courts in this Circuit have held that the OPLA abrogated claims alleging affirmative misrepresentations where the claims were "based upon a duty to warn." *See Johnson v. Eli Lilly & Co.*, 2015 WL 1120009, *2 (S.D. Ohio) (dismissing fraudulent misrepresentation claim based on statements about drug's safety in promotional materials); *Hendricks v. Pharmacia Corp.*, 2014 WL 2515478, *4 (S.D. Ohio) (dismissing fraud and consumer protection claim based on statements about drug's alleged risks).

"Drawing reasonable inferences in Plaintiffs' favor," as I am required to do on a motion to dismiss, plaintiffs' misrepresentation claims allege, in part, that defendants violated a "general duty not to deceive." *Elward, supra*, 264 F. Supp. 3d at 896. Indeed, plaintiffs allege that defendants affirmatively misrepresented Subsys's safety and its appropriate use. (*See, e.g.*, Doc. 1-2 at 8, ¶ 42; *id.* at 17, ¶ 91; *id.* at 20, ¶ 111). Accordingly, the OPLA does "not necessarily abrogate[]" the misrepresentation claims to the extent they rely on these allegations of deception. *Stratford, supra*, 2008 WL 2491965 at *8.

The complaint does not, however, "state the time, place and context of the alleged misrepresentations." *Id.* at *8. (*See, e.g.*, Doc. 1-2 at 8, ¶ 42; *id.* at 17, ¶ 91; *id.* at 20, ¶ 111). Plaintiffs, therefore, have not met the requirement under Fed. R. Civ. P. 9(b) to plead fraud with particularity. Accordingly, I dismiss the misrepresentation claims without prejudice to plaintiffs' right file an amended complaint. *See Stratford, supra*, 2008 WL 2491965 at *8-9.[7]

[7] Plaintiffs argue that the OPLA does not abrogate their negligence claim because it "concern[s] active misrepresentation." (Doc. 12 at 17). I decline to entertain this argument because I dismissed that claim on FDCA preemption grounds. Consistent with this opinion, if plaintiffs file an amended complaint, they may choose to include those "active misrepresentation" allegations in their misrepresentation claims. (*See* Doc. 1-2 at 7, ¶¶ 36, 37).

C. The OPLA Does Not Abrogate Plaintiffs' OCSPA Claim to the Extent They Allege Active Misrepresentation

Defendants also argue that I must dismiss plaintiffs' claim under the Ohio Consumer Sales Practices Act (OCSPA), Ohio Rev. Code §§ 1345.01, *et seq.*, as "a product-liability claim subject to OPLA preemption." (Doc. 6-1 at 16) (collecting cases).

"[T]he OPLA has . . . been held to preempt claims under the OCSPA, where the OCSPA claims are primarily rooted in product liability claims." *Mitchell v. Proctor & Gamble*, 2010 WL 728222, *4 (S.D. Ohio). The court in *Mitchell*, following a brief analysis, held that the OPLA abrogated plaintiff's OCSPA claims because they were "essentially products liability claims." 2010 WL 728222 at *5.

The OPLA unquestionably abrogates plaintiffs' OCSPA claim to the extent it relies on plaintiffs' allegation that defendants failed to warn of Subsys's "serious and dangerous side effects." *Stratford*, *supra*, 2008 WL 2491965 at *8. (*See* Doc. 1-2 at 19, ¶ 107).

But neither *Mitchell*, *supra*, nor any of the cases defendants cite provides guidance about how to determine whether an OCSPA claim is "primarily rooted in product liability claims." *See* 2010 WL 728222 at *5. Nor do those cases discuss whether the OPLA abrogates OCSPA claims alleging violations of a general duty not to deceive. The closest case is *Blake v. Interneuron Pharmaceuticals*, 1998 WL 35307753, *1 (S.D. Ohio), where the court summarily held that the OPLA abrogated an OCSPA claim based on a drug manufacturer's "false and/or misleading advertising, representations and statements." *Id.*

Plaintiffs' OCSPA claim, in part, relies on allegations that that defendants "knowingly made false and misleading statements" about Subsys's safety "in violation of" the OCSPA. (Doc. 1-2 at 19, ¶ 105). Accordingly, the OCSPA claim, like plaintiffs' misrepresentation claims, depends on alleged violations of a "general duty not to deceive." *See Stratford*, *supra*, 2008 WL

2491965 at *8. The OPLA does not abrogate the OCSPA claim to the extent it relies on such allegations. *See id.*; *Hutchens, supra*, 2016 WL 5661582 at *12; *Elward, supra*, 264 F. Supp. 3d at 896.

The opinion in *Blake, supra*, does not convince me otherwise. That case is over twenty years old, provides scant analysis, and is not mandatory authority. *See* 1998 WL 35307753.

I therefore find that the OPLA does not abrogate plaintiffs' OCSPA claim to the extent it is based on alleged active misrepresentation.[8]

III. Plaintiffs' OCSPA Claim Is a Personal Injury Claim and Must Be Dismissed

Defendants also argue that "Plaintiffs' OCSPA claim (Count 8) should be dismissed" because it is a personal injury claim. (Doc. 6-1 at 17-18).

The OCSPA "do[es] not apply to . . . [c]laims for personal injury." Ohio Rev. Code § 1345.12(C). The statute "will bar . . . claims that require proof of a personal injury in order to establish a[n O]CSPA violation." *Whitaker v. M.T. Auto., Inc.*, 855 N.E.2d 825, 833 (Ohio 2006). An OCSPA claim is viable, however, where a plaintiff's injuries are "a consequence of . . . [O]CSPA violations." *Id.*

Citing *Whitaker, supra*, plaintiffs argue that Michael's injuries resulted from defendants' alleged OCSPA violation. (Doc. 12 at 20). Defendants' counter that the gravamen of plaintiffs' claim is a personal injury suit. (Doc. 6-1 at 17-18). I agree with defendants.

"In enacting the OCSPA, the legislative intent was to preclude the fleecing of Ohio consumers by unscrupulous suppliers who misrepresented their products or services." *Chamberlain v. Am. Tobacco Co.*, 1999 WL 33994451, *17 (N.D. Ohio) (Gaughn, J.) (internal

[8] As explained *infra*, however, independent grounds exist to dismiss the OCSPA claim.

quotations and citation omitted). OCSPA claims, then, "involve economic harm to consumers" not "a supplier's misrepresentations which resulted in physical harm to a consumer." *Id.*

The court in *Chamberlain, supra*, dismissed plaintiffs' OCSPA claim based on their physical harm that defendant tobacco companies' "deceptive and fraudulent business practices" allegedly caused. *Id.* at *16. Similarly, the court in *Utz v. Howmedica Osteonics, Corp.*, 2008 WL 11378848, *4-5 (N.D. Ohio) (Oliver, J.) dismissed plaintiffs' OCSPA claim based on one plaintiff's injuries from allegedly defective spinal rods. The court denied plaintiffs' OCSPA claim for medical expenses because such "expenses derive directly from [the treated plaintiff's] physical injury." *Id.*

Likewise, here, "[t]he predominate harm, which is the gravamen of this case, is the alleged physical harm associated with" Michael's use of Subsys. *See Chamberlain, supra*, 1999 WL 33994451 at *7. Plaintiffs' OCSPA claim, therefore, is barred as one for personal injury.

Plaintiffs argue that, at a minimum, they may recover the "costs of the prescriptions based on fraudulent marketing and the like." (Doc. 12 at 20 (internal citations omitted)). I disagree. The court in *Chamberlain, supra*, rejected a similar request for "restitution of the purchase price" of the tobacco products. I likewise reject plaintiffs' argument.[9]

[9] Defendants cite *Utz, supra,* to argue that plaintiffs cannot recover their prescription costs. (Doc. 13 at 15 (citing 2008 WL 11378848 at *4-5)). That case, as it relates to restitution for the cost of the product at issue, is unhelpful. The plaintiffs in *Utz* sought restitution for the cost of the defective spinal rods. The court denied that request, not because the rods resulted in the plaintiff's injury, but because they "were not a separate economic loss and [were] instead part of Plaintiffs' medical expenses. There is no indication that Plaintiffs purchased these rods apart from the surgery." 2008 WL 11378848 at *5. Here, however, Michael purchased his Subsys prior to his overdose, not as a course of treatment for his overdose.

IV. Plaintiffs' NIED, Loss of Consortium, and Unjust Enrichment Claims

Defendants argue that plaintiffs' unjust enrichment, loss of consortium, and NIED claims must be dismissed. These claims are derivative of plaintiffs' other allegations. That is, plaintiffs claim that, because of defendants' wrongdoing: 1) defendants were unjustly enriched; 2) Julie "lost the love and affection and support of her husband;" (Doc. 1-2 at 21-22, ¶ ¶ 120); and 3) Julie "suffered . . . severe emotional distress" when she found Michael unresponsive from his overdose (*id.* at 22, ¶¶ 123-24).

To the extent these claims rely on claims that are preempted, abrogated, or otherwise subject to dismissal, they cannot survive. Insofar as they rely on plaintiffs' remaining claims, however, they remain viable. Thus, I grant defendants' motion to dismiss these claims to the extent they are based on plaintiffs': negligence claim, common-law strict liability claims, statutory strict liability claim based on inadequate warning, misrepresentation claims, [10] and OCSPA claim. I overrule the motion to dismiss these claims to the extent they rely on plaintiffs' statutory design defect claim.

V. Plaintiffs' Request to Amend

Plaintiffs, in alternative to their opposition to defendants' motion, "specifically invoke Rule 15 of the Federal Rules of Civil Procedure and move . . . for leave to amend their Complaint." (Doc. 12 at 20). Defendants argue that plaintiffs' "attempt to hedge their bets is improper." (Doc. 13 at 1 n.1). I agree with defendants.

[10] Because I have dismissed the misrepresentation claims without prejudice, plaintiffs may re-raise the unjust enrichment, loss of consortium, and NIED claims, insofar as they rely on the misrepresentation claims, in an amended complaint.

"A party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2).

Here, however, plaintiffs have not properly moved to amend their complaint or articulated grounds justifying such an amendment. "Rather, in opposition to the motion to dismiss, Plaintiffs requested that they be permitted to amend the complaint in the event that the Court found it to be deficient." *Begala v. PNC Bank Nat. Ass'n*, 214 F.3d 776, 783 (6th Cir. 2000) (quoting district court); *see also PR Diamonds, Inc. v. Chandler*, 364 F.3d 671, 699 (6th Cir. 2004) ("What plaintiffs have stated, almost as an aside to the district court in a memorandum in opposition to the defendant's motion to dismiss is also not a motion to amend.") (quoting *id.*). "Plaintiffs [are] not entitled to an advisory opinion from the Court informing them of the deficiencies of the complaint and then an opportunity to cure those deficiencies." *Begala*, *supra*, 214 F.3d at 784.

I therefore deny plaintiffs' sweeping request.[11]

Conclusion

It is, therefore,

ORDERED THAT

1. Defendants Insys Therapeutics, Inc., Insys Pharma, Inc., and Insys Manufacturing, LLC's motion to dismiss (Doc. 6) be, and the same hereby is granted in part and denied in part;

[11] Consistent with this opinion, however, I dismiss plaintiffs' misrepresentation claims without prejudice to their right to seek leave to amend. *See, e.g., Stratford*, *supra*, 2008 WL 2491965 at *8-9 (dismissing complaint without prejudice to plead fraud and misrepresentation with particularity).

2. Plaintiffs' second, seventh, and ninth causes of action are dismissed without prejudice;
3. Plaintiffs' sixth, tenth, eleventh, and twelfth causes of action remain pending;
4. Plaintiffs' thirteenth cause of action is dismissed without prejudice to plaintiffs' right to seek punitive damages in further proceedings;
5. Plaintiffs' remaining claims are dismissed with prejudice.

So ordered.

/s/ James G. Carr
Sr. U.S. District Judge